

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02326 MDL No. 2326</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**CROSS-NOTICE OF VIDEOTAPED DEPOSITION  
OF PERSON(S) MOST QUALIFIED ON TOPICS LISTED IN “EXHIBIT A”**

**PLEASE TAKE NOTICE** that, pursuant to Rule 30 of the Federal Rules of Civil Procedure, Plaintiff shall take the discovery deposition upon oral examination of the Person(s) Most Qualified on Topics Listed in Exhibit “A” on March 8, 2017, at 9:30 a.m. at the DoubleTree, 5400 Computer Drive, Westborough, MA 01581, at which time and place you may participate.

The deposition shall be recorded by stenographic means before a person duly authorized to administer oaths and will be videotaped. The deposition is scheduled to continue from day to day until completed.

This deposition is cross-noticed in the above-captioned matter pursuant to Federal Rules of Civil Procedure.

Respectfully submitted,

**THE MOSTYN LAW FIRM**

/s/ Mark Sparks

Mark Sparks

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**ATTORNEYS FOR PLAINTIFFS**

## **EXHIBIT “A”**

The deponent(s) should be the person(s) most qualified to testify on behalf of Boston Scientific Corporation (“BSC”) regarding the following topics:

### **Mesh Materials**

1. The decision to use heavyweight mesh to launch BSC’s pelvic organ prolapse (“POP”) devices in 2008.
2. The decision to change the material used to manufacture BSC’s POP devices to lightweight mesh, and the date of that decision.
3. The availability and BSC’s awareness of lightweight mesh prior to the launch of BSC’s POP devices in 2008, including, but not limited to when Proxy first approached BSC with the product improvement of a reduced weight or lightweight polypropylene surgical mesh and the substance of the discussions with Proxy.
4. The literature available on lightweight mesh prior to the launch of BSC’s POP devices in 2008.
5. The criteria used to select Marlex HGX-030-01 polypropylene to manufacture BSC’s transvaginal mesh devices.
6. All raw materials BSC considered for use in its transvaginal mesh devices.
7. The chemical make-up of and Marlex HGX-030-01, including but not limited to, type and quantity of stabilizers used, type and quantity of catalyst and additive packages used, any changes to the chemical make-up of Marlex HGX-030-01 while it was used by BSC to manufacture its transvaginal mesh devices, and any formulary lock in place with Phillips Sumika Polypropylene Company and any agreements not to use Marlex HGX-030-01.
8. The resin(s) used to make TVT and Trelex, including, but not limited to manufacturer, particular grade of the resin(s) and the extrusion process, including, but not limited to, processing aid(s) used to extrude fiber from the resin, chemical remnants on TVT and Trelex.
9. Any testing of BSC’s mesh materials post-processing to determine degradation or change in chemical make-up, including but not limited to, consumption of stabilizers.
10. The source of the polypropylene resin and fiber BSC used to manufacture its stress urinary incontinence (“SUI”) devices prior to launching the devices.
11. The historical use of Marlex, including grade(s) historically used and the chemical make-up, including but not limited to catalyst and additive packages, metal contents, and

contaminants left over from manufacturing of the grade(s) of Marlex, to support statements that its been used safely since 1950s.

12. At the time of development of BSC's POP and SUI products, whether the material used to make the mesh predated the development of the POP and SUI products.

13. The reaction of polypropylene when exposed to:

- a. chemicals and chemical compounds produced in the human body, including, but not limited to those produced by the body's inflammatory response or reactive oxidative stress.
- b. bacterial infection,
- c. oxidants, chemicals, and chemical compounds prior to implantation during storage, processing, and post-processing.

14. The design and materials in the hybrid mesh product contemplated by BSC, the reasons the hybrid product was not marketed.

15. The physical characteristics of the resin used in BSC's POP and SUI products.

16. The physical characteristics of the fiber used in BSC's POP and SUI products, including, but not limited to, the weave pattern, fiber diameter, and any spin finishes used during processing.

17. The relative crystallinity of the polypropylene used in BSC's transvaginal mesh products and whether that polypropylene is, or ever has been, nucleated, compared to the amorphous areas of the polypropylene.

18. Long term stability, processing stability, and long term heat stability of the resin and processed yarn used in BSC's POP and SUI products, BSC's POP and SUI products after they are weaved, and BSC's mesh products after they are sterilized.

#### **Mesh Properties, Characteristics, and Testing**

19. At the time BSC developed and launched each of its transvaginal mesh devices, the shelf life of the polypropylene resin BSC used to manufacture the devices, and all changes to the shelf life of the resin since each product's launch.

20. At the time BSC developed and launched each of its transvaginal mesh devices, the shelf life of the monofilament fiber BSC used to manufacture the devices, and all changes to the shelf life of the monofilament fiber since each device's launch.

21. At the time BSC developed and launched each of its transvaginal mesh devices, the shelf life of the woven mesh BSC used to manufacture the devices, and all changes to the shelf life of the woven mesh since each product's launch.

22. At the time BSC developed and launched each of its transvaginal mesh devices, the shelf life of the specific transvaginal mesh product, and all changes to the shelf life since each product's launch.

23. How shelf life for the product and each component of the device, including the resin, monofilament fiber, and woven mesh, is determined, and how any changes to the shelf life are determined.

24. The biomechanical properties of lightweight mesh compared to the vagina, including but not limited to, tensile strength, max strain percentage, and elasticity and/or stiffness.

25. At the time of development of BSC's POP and SUI products, the shelf life of any material used to make the POP and SUI products.

26. Specifications and/or properties of BSC's stress urinary incontinence (SUI) devices (1) at the time of development and launch, and (2) currently on the market, including, but not limited to:

- a. Pore size;
- b. Tensile Strength;
- c. Elasticity;
- d. Shelf life;
- e. Surface area;
- f. Surface area ratio;
- g. Interstices;
- h. Mesh Density (g/m<sup>2</sup>)
- i. Molecular Weight;
- j. Melt Flow Index;
- k. Heat Deflection Temperature;
- l. Hardness;
- m. Notched and Unnotched Izod Impact Strength;
- n. Storage Condition Requirements;
- o. Packaging Requirements; and
- p. Sterilization Requirements.

27. Specifications and/or properties of BSC's pelvic organ prolapse (POP) devices (1) at the time of development and launch, and (2) currently on the market, including, but not limited to:

- a. Pore size;
- b. Tensile Strength;
- c. Elasticity;
- d. Shelf life;
- e. Surface area;
- f. Surface area ratio;
- g. Interstices;
- h. Mesh Density (g/m<sup>2</sup>);
- i. Molecular Weight;

- j. Melt Flow Index;
- k. Heat Deflection Temperature;
- l. Hardness;
- m. Notched and Unnotched Izod Impact Strength;
- n. Storage Condition Requirements;
- o. Packaging Requirements; and
- p. Sterilization Requirements.

28. Specifications and/or properties of Trelex mesh, including, but not limited to:

- a. Pore size
- b. Tensile Strength;
- c. Elasticity;
- d. Shelf life;
- e. Surface area;
- f. Surface area ratio;
- g. Interstices;
- h. Mesh Density (g/m<sup>2</sup>);
- i. Molecular Weight;
- j. Melt Flow Index;
- k. Heat Deflection Temperature;
- l. Hardness;
- m. Notched and Unnotched Izod Impact Strength;
- n. Storage Condition Requirements;
- o. Packaging Requirements; and
- p. Sterilization Requirements.

29. Specifications and/or properties of Polyform mesh, including, but not limited to:

- a. Pore size;
- b. Tensile Strength;
- c. Elasticity;
- d. Shelf life;
- e. Surface area;
- f. Surface area ratio;
- g. Interstices;
- h. Mesh Density (g/m<sup>2</sup>);
- i. Molecular Weight;
- j. Melt Flow Index;
- k. Heat Deflection Temperature;
- l. Hardness;
- m. Notched and Unnotched Izod Impact Strength;
- n. Storage Condition Requirements;
- o. Packaging Requirements; and
- p. Sterilization Requirements.

30. Tests and procedures BSC used to test its transvaginal mesh for degradation post-processing.

31. The ability of microphage and white blood cells to attack bacteria in the interstices which may contaminate vaginal mesh.

32. Considerations and concerns to prevent contamination of polypropylene mesh when it passes transvaginally to prevent bacterial infection, including any design specification to prevent or eliminate bacterial infection.

**Mesh Complications & Removal**

33. BSC's knowledge and awareness, prior to launch of its SUI and POP devices, of following complications of mesh made from synthetics, including, but not limited to, polypropylene:

- a. Mesh erosion;
- b. Mesh shrinkage;
- c. Mesh degradation;
- d. Mesh migration;
- e. Chronic pain;
- f. Dyspareunia;
- g. Inflammation;
- h. Fistulae;
- i. Organ perforation;
- j. Recurrence;
- k. Hematoma;
- l. Infection;
- m. Bacteria;
- n. Toxicity;
- o. Scarring;
- p. Colonization;
- q. Dehiscence
- r. Adhesion;
- s. Exposure;
- t. Contraction;
- u. Implant rejections;
- v. Contamination;
- w. Encapsulation; and
- x. Proliferation.

34. BSC's knowledge and awareness, prior to launch of its SUI and POP devices, that lightweight mesh was associated with less shrinkage and less complications.

35. BSC's knowledge and awareness, prior to launch of its SUI and POP devices, that lightweight mesh has less surface area and consequently, the foreign body response is significantly reduced.

36. BSC's knowledge and awareness, prior to launch of its SUI and POP devices, that the implants would be contaminated by vaginal flora and the mesh design increases the bacterial adhesion, reduces bacterial clearance, and favors colonization.

37. BSC's knowledge and awareness, prior to launch of its SUI and POP devices, regarding the failure rate of mesh made from synthetics, including, but not limited to, polypropylene.

38. BSC's knowledge and awareness, prior to launch of its SUI and POP devices manufactured with polypropylene, regarding the vagina being a clean contaminated site.

39. BSC's knowledge and awareness, prior to launch of its SUI and POP devices manufactured with polypropylene, regarding the inability to avoid bacterial contamination of the graft during insert.

40. BSC's considerations, prior to launch of its SUI and POP devices, regarding disclosures to hospitals, physicians, and patients about the failure rate of mesh made from synthetics, including, but not limited to, polypropylene.

41. BSC's knowledge and awareness, prior to launch of its SUI and POP devices, regarding removal of mesh made from synthetics, including, but not limited to polypropylene, the inability to remove the mesh and complications resulting from attempting to remove the mesh.

**Mesh Component Manufacturers**

46. The relationship between BSC, Proxy Biomedical, Luxilon Industries, NV, and MedVenture Technologies.

47. The reason(s) BSC switched vendors from Secant to Proxy Biomedical.

48. The reason(s) BSC switched vendors from Jarden Applied Materials to Luxilon Industries, NV.



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**CERTIFICATE OF SERVICE**

I hereby certify that on March 7, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

**THE MOSTYN LAW FIRM**

/s/ Mark Sparks

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